Bayer HealthCare
Diabetes Care

JUN 28 2012

510(k) Summary K121087

According to the requirements of 21 CFR 807.92, the following information is being submitted in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

1) Submitter	Roger Sonnenburg Bayer Healthcare Diabetes Care 430 S. Beiger St. Mishawaka, IN 46544 Telephone: 574-256-3441 Date prepared: June 26, 2012
2) Device name:	Trade name: Contour NEXT USB Blood Glucose Monitoring System Meter: Contour NEXT USB Blood Glucose Meter Strips: Contour NEXT Blood Glucose Test Strips Controls: Contour NEXT Control Solution Classification name: NBW, Blood Glucose Test System, Over-the-Counter (21 CFR § 862.1345); LFR, Glucose Dehydrogenase; JJX, Single Analyte Controls
3) Predicate device:	Contour NEXT LINK Wireless Glucose Monitoring System (K110894)
4) Device description:	The Contour NEXT USB Blood Glucose Monitoring System consists of a small handheld blood glucose meter that is substantially equivalent in look and feel to the predicate system, Contour® Next Wireless Blood Glucose Meter, (K110894). The system also consists of dry reagent test strips used for the measurement of glucose in capillary whole blood and includes liquid controls to check the performance of the system. The chemical principle of the system is based on measurement of electrical current caused by the reaction of glucose in the blood with chemicals on the reagent strip. The blood sample is drawn into the tip of the reagent strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) enzyme on the reagent strip. The electrons generated by this reaction are shuttled to an electrode by a mediator chemical, producing a current that is proportional to the glucose in the sample.

5) Intended Use

The Contour® NEXT USB blood glucose monitoring system is an over the counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The Contour® NEXT USB blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The Contour® NEXT USB blood glucose monitoring system may be used as an aid to monitor the effectiveness of a diabetes control program and is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Contour® NEXT Test Strips are for use with the Contour® NEXT USB blood glucose monitoring system for the quantitative measurement of glucose in whole blood. The Contour® NEXT Controls are for use with the Contour® NEXT USB blood glucose monitoring system to check that the meter and test strips are working properly.

Glucofacts® Deluxe Diabetes Management Software is an over-the-counter software program intended for use by health care professionals and patients with diabetes for viewing and printing reports that display blood sugar readings from Bayer's Contour and Breeze families of meters.

Data demonstrating substantial equivalence

The Contour NEXT USB Blood Glucose Monitoring System was tested in accordance with ISO 15197:2003. Analytical performance testing included system accuracy, repeatability, intermediate precision and linearity testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The data demonstrates that the system is substantially equivalent to the predicate device.

System Accuracy

The following tables show that the device met the system accuracy requirement as spelled out in ISO 15097:2003, using three lots of test strips.

System Accuracy results for glucose concentrations <75 mg/dL
Number and percent of glucose results within stated limits of the reference method.

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
65 of 78 (83.3%)	78 of 78 (100%)	78 of 78 (100%)

System Accuracy results for glucose concentrations ≥75 mg/dL
Number and percent of glucose results within stated limits of the reference method.

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
390 of 522 (74.7%)	512 of 522 (98.1%)	522 of 522 (100%)	522 of 522 (100%)

Regression Statistics

The table below shows that the Contour NEXT USB system compares well with the glucose reference system.

Least Squares Regression Statistics

*Proportional weighting: Syx = k * reference*

Regression Equation	y = 0.96(x) + 2.1
95% Confidence Interval of Slope	0.960 ± 0.005 (0.955 to 0.965)
95% Confidence Interval of Intercept	2.087 ± 0.398 (1.690 to 2.485)
r^2	0.9957
Syx	3.62%
N	600

Repeatability
300 venous blood tests per level (100 tests with each of three lots of test strips)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	47	0.8	1.8
80	87	1.3	1.5
130	131	1.9	1.5
210	211	2.8	1.3
330	342	6.4	1.9

Intermediate Precision
300 Control Solution tests per level (100 tests with each of three lots of test strips)

Control Level	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1	45	0.9	2.0
Level 2	133	2.0	1.5
Level 3	397	6.6	1.7

User Performance Evaluation

Subject and Professional Fingertip Results for Glucose Concentration <75 mg/dL

Tester	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Subject	8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)
Professional	8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)

Subject and Professional Fingertip Results for Glucose Concentration ≥75 mg/dL

Tester	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Subject	152 of 196 (77.6%)	188 of 196 (95.9%)	193 of 196 (98.5%)	195 of 196 (99.5%)
Professional	151 of 196 (77.0%)	194 of 196 (99.0%)	196 of 196 (100%)	196 of 196 (100%)

Design verification and validation testing confirmed that the performance, safety and effectiveness of the Contour NEXT USB Blood Glucose Monitoring System is equivalent or better than the predicate device.

Conclusion

The Contour NEXT USB Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate device, Contour NEXT LINK Wireless Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bayer HealthCare LLC, Diabetes Care
c/o Roger Sonnenburg
430 South Beiger St.
Mishawaka, IN 46544

JUN 28 2012

Re: k121087
Trade Name: Contour NEXT USB Blood Glucose Monitoring System; Glucofacts® Deluxe Diabetes Management Software
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: LFR, NBW, JJX, JQP
Dated: May 30, 2012
Received: June 1, 2012

Dear Mr. Sonnenburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K12XXXX: K121087

Device Name: CONTOUR® NEXT USB Blood Glucose Monitoring System

Indications for Use:

The CONTOUR® NEXT USB Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR® NEXT USB Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The CONTOUR® NEXT USB Blood Glucose Monitoring System may be used as an aid to monitor the effectiveness of a diabetes control program and is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Contour® NEXT Test Strips are for use with the CONTOUR® NEXT USB Blood Glucose Monitoring System for the quantitative measurement of glucose in whole blood. The Contour® NEXT Controls are for use with the CONTOUR® NEXT USB Blood Glucose Monitoring System to check that the meter and test strips are working properly.

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Prescription Use X (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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